

the scope of a federal law mandating the sale of covered outpatient drugs at a specified price to “covered entities”—hospitals and clinics meeting specified statutory criteria.

2. H.B. 1056 directly conflicts with Congress’s carefully designed federal program and is therefore preempted by federal 340B law. The Maryland law requires manufacturers to provide the federal 340B discount on an unlimited number of transactions involving for-profit pharmacies (known as “contract pharmacies”). Several federal courts (including the Third Circuit, the D.C. Circuit, and the District Court for the District of Columbia) have held that federal 340B law does *not* require manufacturers to recognize an unlimited number of contract pharmacies. Yet that is precisely what Maryland’s H.B. 1056 purports to mandate, greatly expanding the scope of the federal discounting obligation in conflict with federal law.

3. H.B. 1056 further conflicts with the federal 340B enforcement process by purporting to create its own state-level 340B enforcement mechanism. Congress created two exclusive pathways to resolve disputes arising under the 340B statute: (i) direct enforcement by federal agencies, and (ii) an Administrative Dispute Resolution process that serves as the exclusive means for regulated entities to bring narrow types of private claims relating to 340B law. Congress gave no authority to the States to administer, interpret, or enforce any aspect of the 340B Program. Yet H.B. 1056 purports to do exactly that.

4. The Maryland law also is preempted by federal drug laws, including the Food, Drug, and Cosmetic Act (FDCA), the federal Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Act, and the federal patent laws. In these statutes, Congress spelled out a grand bargain: Brand name manufacturers are driven to research, develop, and bring to market pharmaceutical products on the promise that they will obtain federally protected, exclusive rights to sell their products for specified periods of time. Once those periods

expire, generic manufacturers are permitted to rely upon the drug development work done by innovator manufacturers by obtaining streamlined approval of generic products. H.B. 1056 requires Novartis to make its drugs that are not covered by the federal 340B framework available at heavily discounted prices *before* those federally protected exclusivity periods have run, undermining the bargain carefully constructed by federal law. That frustrates the purposes of Congress.

5. Finally, Maryland's H.B. 1056 violates the dormant Commerce Clause by fueling an economically protectionist regime. The state law unlawfully regulates wholly out-of-state transactions between manufacturers and wholesalers, and it does so with both discriminatory intent and discriminatory effect. It also privileges in-state pharmacies' economic interests at the expense of out-of-state manufacturers.

6. Absent immediate judicial intervention enjoining H.B. 1056, Novartis will suffer irreparable harm. Once the law becomes effective on **July 1, 2024**, Novartis will risk violating Maryland law merely by continuing to implement a contract pharmacy policy that has already been expressly declared lawful by other federal courts applying the federal 340B law. If H.B. 1056 is not enjoined, Novartis will continue to suffer severe irreparable harm and loss of its constitutional rights on an ongoing basis. Novartis therefore requests a preliminary injunction enjoining enforcement of H.B. 1056 pending a decision on the merits.

7. For all of these reasons, Novartis brings this action seeking a declaration that H.B. 1056 is unconstitutional and a temporary, preliminary, and/or permanent injunction barring Defendants from enforcing H.B. 1056 against Novartis.

PARTIES

8. Plaintiff Novartis is a corporation organized in Delaware with its principal place of business at 59 Route 10, East Hanover, New Jersey 07936. Novartis's purpose is to reimagine medicine to improve and extend people's lives.

9. Defendant Anthony G. Brown is the Attorney General for the State of Maryland and is responsible for administering and enforcing the provisions of H.B. 1056. Defendant Brown maintains an office at 200 St. Paul Place, Baltimore Maryland 21202.

10. Defendant Kristopher Rusinko is the President of the Maryland Board of Pharmacy, also responsible for administering and enforcing the provisions of H.B. 1056. Defendant Rusinko maintains an office at 4201 Patterson Avenue, No. 5, Baltimore Maryland 21215.

JURISDICTION AND VENUE

11. Jurisdiction in this Court is grounded upon and proper under 28 U.S.C. § 1331, in that this civil action arises under the laws of the United States, and under 28 U.S.C. §§ 2201–02, in that there exists an actual justiciable controversy between the parties as to which Plaintiff requires a declaration of its rights by this Court and injunctive relief.

12. This Court also has inherent equitable powers to enjoin the actions of state officials that contradict the U.S. Constitution and federal law. *Ex parte Young*, 209 U.S. 123, 159–160 (1908); *United States v. South Carolina*, 720 F.3d 518, 526 (4th Cir. 2013).

13. Venue is proper in this Court under 28 U.S.C. § 1391(b)(1) and (2) because one or more defendants reside in this district and/or because a substantial part of the events or omissions giving rise to the claim occurred in this district. Novartis sells its products to covered entities located in this District.

FACTUAL BACKGROUND

I. Statutory and Regulatory Background

14. Congress created the 340B Drug Pricing Program in 1992. The program requires participating pharmaceutical manufacturers to provide deep discounts on certain drugs to specified types of healthcare providers—known as “covered entities”—as a condition of the availability of federal payments for such drugs under Medicaid and Medicare Part B. 42 U.S.C. § 256b.

15. At its core, the 340B Program requires a participating pharmaceutical manufacturer to charge a covered entity no more than the 340B ceiling price—a discounted price calculated under a prescribed statutory formula—for each unit of a covered outpatient drug. *Id.* §§ 256b(a)(1), (a)(4), (b)(1). A participating manufacturer “shall offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.” *Id.* § 256b(a)(1).

16. The 340B Program is overseen by the federal Department of Health and Human Services (HHS) and its sub-agency, the Health Resources and Services Administration (HRSA). To participate in the 340B Program, a manufacturer must enter a Pharmaceutical Pricing Agreement (PPA) with the federal government. 42 U.S.C. § 256b(a)(1).

17. The “applicable ceiling price,” or “340B price,” is a steeply discounted rate—as low as one penny—calculated under a prescribed statutory formula. *See* 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1210, 1214-15 (Jan. 5, 2017); 42 U.S.C. § 256b(a)(2).

18. Congress intentionally limited the scope of sales that would trigger such a severe discount to those drugs “purchased by a covered entity.” 42 U.S.C. § 256b(a)(1). The statute carefully defined the term “covered entity” in a specific and exhaustive way, listing 15 types of

entities that qualify for the discount. *Id.* § 256b(a)(4) (listing federal grantees, black lung clinics, family planning projects, and specified types of non-profit hospitals). The statute does not require that the 340B discount be given to entities not included within the definition of “covered entity.”

19. In the first several years of the program, covered entities dispensed 340B-purchased drugs exclusively through their own in-house pharmacies. But over time, covered entities sought to be able to dispense 340B-purchased drugs through contractual arrangements with third-party pharmacies (so-called “contract pharmacies”) as well. Under these arrangements, instead of drugs being shipped to the covered entity for dispensing by its in-house pharmacy, drugs are shipped to the contract pharmacy—often a large, national chain—for dispensing there.

20. Contract pharmacy arrangements, including those in Maryland, traditionally involve a “virtual inventory” or “replenishment” model. Under this model, the contract pharmacy starts with an inventory of commercially purchased product and dispenses all units of the drug from this common inventory, regardless of whether the individual to whom a unit is dispensed is a patient of the covered entity. That is because the contract pharmacy itself typically has not determined at the time of dispensing whether the individual receiving the prescription is a “patient” of the covered entity. That determination is made afterward. Where it believed, based on an opaque formula generally not shared with the manufacturer, that the individual is a covered-entity patient, the covered entity purchases a “replenishment” unit at the 340B price and directs shipment to the contract pharmacy—which commingles the 340B-purchased unit with commercially purchased units in its common inventory. The 340B replenishment unit is treated as if it had been purchased at the commercial price—and thus is available for dispensing to anyone, including a non-patient of the covered entity—even though it has in fact been purchased at the 340B price. *See Novartis Pharms. Corp. v. Johnson*, No. 21-5299 (D.C. Cir. May 21, 2024) (“Slip Op.”), at

16–18; *see also* HHS OIG, Memorandum Report: Contract Pharmacy Arrangements in the 340B Program, OEI-05-13-00431 at 5 (Feb. 4, 2014), *available at* <https://oig.hhs.gov/oei/reports/oei05-13-00431.pdf>.

21. The statute provides for only two enforcement mechanisms. First, the statute provides for the imposition of civil monetary penalties (CMPs) on manufacturers that knowingly and intentionally charge a covered entity a price for a 340B drug that exceeds the ceiling price. 42 U.S.C. § 256b(d)(1)(B)(vi)(III). HRSA has taken the position that implementation of this statutory remedy requires a referral to the HHS Office of Inspector General (OIG).

22. In addition, the statute required the Secretary of HHS to promulgate regulations establishing an ADR process to resolve specific categories of private disputes between covered entities and manufacturers arising under the 340B Program. 42 U.S.C. § 256b(d)(3). The statute specifically describes two narrow claim categories that are funneled to administrative dispute resolution: (1) “claims by covered entities that they have been overcharged for drugs purchased under this section,” and (2) claims by manufacturers relating to duplicate discounts and drug diversion. 42 U.S.C. § 256b(d)(3)(A). In promulgating ADR regulations, the agency has recently interpreted these provisions—rightly or wrongly—to include a claim “that a manufacturer has limited the covered entity’s ability to purchase covered outpatient drugs at or below the 340B ceiling price.” 89 Fed. Reg. 28,643, at 28,657 (Apr. 19, 2024).

23. There are no other enforcement mechanisms contemplated by the 340B statute.

II. HRSA’s Changing Position on Contract Pharmacies

24. Over time, HRSA’s position on contract pharmacies has evolved.

25. In 1996, the agency issued guidance announcing that the agency would not preclude covered entities lacking an in-house pharmacy from entering into a contractual relationship with a

single outside pharmacy to dispense covered outpatient drugs to the covered entity's patients. 61 Fed. Reg. 43,549 (Aug. 23, 1996).

26. In 2010, HRSA issued revised guidance on contract pharmacy arrangements, stating that covered entities may be permitted to “use” an untold number of “multiple pharmacy arrangements”—with no limits on their physical location, and even if the covered entity had its own in-house pharmacy—“as long as they comply with guidance developed to help ensure against diversion and duplicate discounts and the policies set forth regarding patient definition.” 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010). HRSA's 2010 Guidance thus purported to authorize covered entities to enter into a limitless number of contract pharmacy arrangements with any pharmacy located anywhere in the United States.

27. That decision had striking consequences. Over the ensuing years, the number of contract pharmacies receiving and distributing 340B drugs grew at a rapid clip. By 2018, the Government Accountability Office found that the number of contract pharmacies had ballooned from 1,300 in 2010 to nearly 20,000 by 2017. Government Accountability Off., *Drug Discount Program, Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, at 36 (June 2018), <https://www.gao.gov/assets/gao-18-480.pdf>. This report echoed findings from the Department of Health and Human Services' Office of Inspector General, which similarly documented dramatically increased use—and abuse—of 340B discounts through covered entities' contract pharmacy relationships. HHS OIG, *Memorandum Report: Contract Pharmacy Arrangements in the 340B Program*, No. OEI-05-00431 at 9–10, 16 (2014), <https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf>.

28. Neither covered entities nor their contract pharmacies are required to pass on 340B discounts to patients, and often they do not. Instead, covered entities and contract pharmacies are

permitted to (and often do) pocket the discount themselves. Over time, 340B expenditures have swelled as contract pharmacy arrangements, and the profits they generate for covered entities and contract pharmacies alike, proliferated. By 2020, sales of 340B units constituted an estimated 7% of the entire U.S. prescription drug market and 17% of all total U.S. branded outpatient drug sales. Karen Mulligan, *The 340B Drug Pricing Program: Background, Ongoing Challenges and Recent Developments* (Oct. 14, 2021), available at <https://healthpolicy.usc.edu/research/the-340b-drug-pricing-program-background-ongoing-challenges-and-recent-developments>; Eleanor Blalock, *Measuring the Relative Size of the 340B Program*, available at <https://media.thinkbrg.com/wp-content/uploads/2022/06/30124832/BRG-340B-Measuring-Relative-Size-2022.pdf>. In 2022, discounted purchases under the 340B Program hit a record high of approximately \$54 billion—a more than 22% year-over-year increase. *Id.*; see also Adam J. Fein, *The 340B Program Reached \$54 Billion in 2022—Up 22% vs. 2021*, Drug Channels (Sept. 24, 2023).

29. Drug distribution channels are notoriously complex, even before contract pharmacies enter the picture. Most drug manufacturers, including Novartis, sell their drug products to national wholesalers and distributors like Cencora, McKesson, and Cardinal Health. Those transactions take place almost entirely outside of the state of Maryland. Wholesalers and distributors in turn sell the drug products to pharmacies, often again at the national level to chains like Walgreens, CVS, and Rite Aid. These transactions also take place largely outside of the state. Pharmacies then dispense the drugs to patients, including those located in Maryland.

30. When a hospital claims a 340B discount on a drug that was dispensed by a contract pharmacy, the 340B discount does not go directly from the manufacturer to the covered entity. The pharmacy typically supplies its claims data to third party data amalgamators, which attempt to match the pharmacy's transactions against hospitals' medical claims data to identify hospital

patients who visited the pharmacy. The covered entity then submits a chargeback to the wholesaler, which credits the covered entity for the 340B discount. The wholesaler then submits its own chargeback to the manufacturer to account for the difference in price.

III. Novartis's Contract Pharmacy Policy and Resulting Litigation

31. Concerned about ever-increasing abuse through fast-multiplying contract-pharmacy arrangements, in late 2020, Novartis notified HRSA of its plans to implement a contract pharmacy policy. Beginning in November 2020, Novartis explained, it would recognize all contract pharmacies within 40 miles of a covered entity—an area of more than 5,000 square miles—and allow covered entities to seek exemptions based on individual circumstances. Novartis's 40-mile limitation did not apply to covered entities that are federal grantees.

32. In early 2021, HRSA issued a violation letter to Novartis, contending that Novartis's policy violated the statute and demanding immediate compliance with HRSA's view that, at the unilateral direction of a covered entity, a manufacturer is obligated to deliver 340B drugs to any contract pharmacy, on pain of an enforcement action.

33. Upon receiving HRSA's violation letter, Novartis immediately challenged the agency action in the U.S. District Court for the District of Columbia. *See Novartis Pharms. Corp. v. Espinosa*, No. 1:21-cv-01479 (D.D.C.) (filed May 31, 2021). Novartis's challenge was heard alongside a later case brought by United Therapeutics, which had also received a violation letter. *See United Therapeutics Corp. v. Espinosa*, No. 1:21-cv-01686 (D.D.C.).

34. Following full briefing and argument, the District Court vacated HRSA's violation letters and issued a decision rejecting HRSA's purported requirement that manufacturers recognize an unlimited number of contract pharmacies as inconsistent with the language of the 340B statute. *Novartis Pharms. Corp. v. Espinosa*, No. 21-CV-1479, 2021 WL 5161783 (D.D.C. Nov. 5, 2021).

As the District Court explained, HRSA’s enforcement letters rested on the contention that the 340B statute “prohibit[s] drug manufacturers from attaching any conditions to the sales of covered drugs through contract pharmacies,” but that the 340B statute does no such thing. *Id.* at *9. In sum, the District Court held that “[t]he statute’s plain language, purpose, and structure do not prohibit drug manufacturers from attaching any conditions to the sales of covered drugs through contract pharmacies.” *Id.*

35. On May 21, 2024, the D.C. Circuit affirmed, holding that the federal 340B statute’s “requirement to ‘offer’ drugs at a certain ‘price’ does not prohibit distribution conditions, much less require the offeror to accede to any distribution conditions, much less require the offeror to accede to any distribution terms demanded by the offeree.” *Novartis Pharms. Corp. v. Johnson*, No. 21-5299 (D.C. Cir. May 21, 2024) (“Slip Op.”), at 16. The Court thus held that Novartis’s contract pharmacy policy does not violate the federal 340B statute, and affirmed the vacatur of HRSA’s violation letter.

36. In a parallel lawsuit brought by other drug manufacturers, the U.S. Court of Appeals for the Third Circuit likewise rejected the notion that Section 340B requires manufacturers to recognize an unlimited number of contract pharmacy arrangements. *See Sanofi Aventis U.S. LLC v. United States Dep’t of Health & Human Srvs.*, 58 F.4th 696 (3d Cir. 2023). The unanimous Third Circuit panel held unlawful HHS’s efforts to enforce its interpretation of Section 340B against drug manufacturers that imposed delivery conditions on sales to covered entities using contract pharmacies. *Id.* at 699. In so doing, the Third Circuit held that “Section 340B does not require delivery to an unlimited number of contract pharmacies.” *Id.* at 703. It identified multiple structural indicators that confirmed this reading of Section 340B. Critically, the Court noted that “[n]owhere does Section 340B mention contract pharmacies,” and inferred this was done with

intentionality, given that Congress “expressly contemplate[d] drug makers selling discounted drugs through contract pharmacies” in an adjacent provision of the same authorizing legislation relating to another (non-340B) program, but did not include similar language for the 340B program. *Id.* at 703–705. The Third Circuit also rejected the argument that manufacturers are required to deliver their 340B drugs anywhere that covered entities wish, including to third party contract pharmacies, as “one giant leap from the text.” *Id.* at 704. To the contrary, “Congress’s use of the singular ‘covered entity’ in the ‘purchased by’ language suggests that it had in mind one-to-one transactions between a covered entity and a drug maker without mixing in a plethora of pharmacies.” *Id.* Because the “drug makers’ restrictions on delivery to contract pharmacies [did] not violate Section 340B,” the Third Circuit “enjoin[ed] HHS from enforcing against them its reading of Section 340B as requiring delivery of discounted drugs to an unlimited number of contract pharmacies.” *Id.* at 706.

37. Following both the District Court’s and the Third Circuit’s decisions, Novartis announced in April 2023 that it was revising its contract pharmacy policy, effective May 3, 2023. In keeping with both decisions, Novartis’s current policy permits hospital covered entities lacking an in-house pharmacy to select a single contract pharmacy location. Novartis also recognizes any arrangements a hospital covered entity might have with contract pharmacies that the covered entity fully owns and controls. Federal grantee covered entities continue to be exempt. *See* Ex. A (April 3, 2023 Letter to Covered Entities on 340B Contract Pharmacy Policy). Novartis’s revised policy mirrors one of the manufacturer policies that the Third Circuit found lawful, and has now also specifically been found lawful by the D.C. Circuit.

IV. Maryland Enacts Its Own “340B” Legislation.

38. On May 16, 2024, Maryland enacted H.B. 1056, which states that a 340B manufacturer may not “directly or indirectly deny, restrict, prohibit, discriminate against, or otherwise limit the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with or otherwise authorized by a covered entity to receive 340B drugs on behalf of the covered entity.” *See* H.B. 1056 (to be codified at Md. Health Occupations Code § 12-6C-09.1(C)(1)); *see also* H.B. 1056, 2024 Leg., Reg. Sess. (Md. 2024), Revised Fiscal and Policy Note at 1.¹ A “340B drug” is defined as a covered outpatient drug that “has been subject to an offer for reduced prices by a 340B manufacturer under [the federal 340B statute].” H.B. 1056 (to be codified at Md. Health Occupations Code § 12-6C-09.1(A)(4). In plain English: The Maryland statute requires manufacturers like Novartis to provide the 340B discount on transactions that involve contract pharmacies.

39. A violation of H.B. 1056 constitutes an unfair, abusive, or deceptive trade practice under the Maryland Consumer Protection Act (MCPA) subject to specified enforcement actions and penalties therein. *See* H.B. 1056 (to be codified at Md. Health Occupations Code § 12-6C-09.1(D)(1)(I)(1) & Md. Code Ann., Com. Law § 13-301(14)(xlii)). An entity that violates the MCPA is subject to a civil fine of up to \$10,000 for each violation and up to \$25,000 for each repetition of the same violation. *See* Md. Code Ann., Com. Law §§ 13-410(a)-(b). The law imposes criminal penalties as well: A person who violates the MCPA is guilty of a misdemeanor and subject to a fine of up to \$1,000 and/or imprisonment for up to one year. *See* Md. Code Ann., Com. Law § 13-411(a). In addition to those MCPA penalties, H.B. 1056 imposes an additional civil fine of up to \$5,000 per violation, *see* H.B. 1056 (to be codified at Md. Health Occupations

¹ Available at https://mgaleg.maryland.gov/2024RS/fnotes/bil_0006/hb1056.pdf.

Code § 12-6C-09.1(D)(2)(I)), providing that “each package of 340B drugs . . . shall constitute a separate violation.” *Id.* (to be codified at Md. Health Occupations Code § 12-6C-09.1(D)(4)).²

40. Any alleged non-compliance must be investigated by the Office of the Attorney General’s Consumer Protection Division or, as applicable, the Maryland Board of Pharmacy (MBOP). *See id.* (to be codified at Md. Health Occupations Code § 12-6C-09.1(D)(1)(I)(2)); *see also* H.B. 1056, 2024 Leg., Reg. Sess. (Md. 2024), Revised Fiscal and Policy Note at 2, https://mgaleg.maryland.gov/2024RS/fnotes/bil_0006/hb1056.pdf. H.B. 1056 further authorizes, as part of any such investigation, the investigation of an affiliate or a contractor of the 340B manufacturer, including a wholesaler or third-party logistics provider. *See* H.B. 1056 (to be codified at Md. Health Occupations Code § 12-6C-09.1(D)(1)(II)).

H.B. 1056 IS UNLAWFUL

41. H.B. 1056 violates the federal constitution, in numerous respects.

42. As explained below, H.B. 1056 violates the Supremacy Clause and the dormant Commerce Clause of the U.S. Constitution.

V. H.B. 1056 Violates the Supremacy Clause.

43. First, H.B. 1056 is preempted by federal law, under both field and conflict preemption principles.

44. Field preemption exists where (1) Congress’s “framework of regulation [is] ‘so pervasive’ ” that Congress has “left no room for the States to supplement it,” or (2) where there is a “federal interest . . . so dominant that the federal system will be assumed to preclude enforcement

² A “package of 340B drugs” means “the smallest individual saleable unit of product for distribution by a manufacturer or repackager that is intended by the manufacturer for ultimate sale to the dispenser of such product.” *See* H.B. 1056, 2024 Leg., Reg. Sess. (Md. 2024), Revised Fiscal and Policy Note at 2, https://mgaleg.maryland.gov/2024RS/fnotes/bil_0006/hb1056.pdf.

of state laws on the same subject.” *Arizona v. United States*, 567 U.S. 387, 399 (2012) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). State statutes that diminish federal control over enforcement, and detract from a unified regulatory scheme that Congress has established, are especially likely to violate the Supremacy Clause under field preemption principles.

45. The 340B Program is just that sort of integrated federal regulatory scheme. It is a creature of a federal statute in which Congress has set out comprehensive regulatory parameters, closed off the regulatory system from state interference, and supplied an exclusively federal framework for enforcement and dispute resolution. The federal 340B statute mentions states only in passing and even then only in a limited way: The definition of covered entity includes hospitals that are “owned or operated by a unit of State or local government”; “State-operated AIDS drug purchasing assistance program[s] receiving” certain federal “financial assistance”; and “entit[ies] receiving [federal] funds” to treat sexually transmitted diseases or tuberculosis “through a State or unit of local government” are all federally defined covered entities. 42 U.S.C. §§ 256b(a)(4)(E), (K), (L)(i).

46. In crafting the 340B statute, Congress created a comprehensive federal regime—one that carefully defined the types of entities that are entitled to receive the 340B discount, and provides its own enforcement pathways for violations of the statute, including civil penalty assessments, administrative appeal pathways, and audits initiated by the agency and/or manufacturers. *See* 42 U.S.C. §§ 256b(a) and (d)(3)(A)–(B). For that reason, the Supreme Court has held that the federal 340B program is to be administered—and enforced—*solely* by or through the federal government. State law claims seeking to separately enforce the 340B statute are preempted. *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110 (2011).

47. By purporting to create a separate, state-specific pathway that adjusts the contours of the federal 340B requirements—altering when the discount is owed, and overriding federal restrictions on who can enforce it—H.B. 1056 runs afoul of the Supreme Court’s admonition that using state law to enforce federal 340B requirements is “incompatible with the statutory regime.” *Astra*, 563 U.S. at 113. Congress has left “no room for the States to supplement it[s]” federal regulatory scheme. *Arizona v. United States*, 567 U.S. 387, 399 (2012).

48. Field preemption also exists when a federal interest is so dominant that it must be assumed the federal system precludes enforcement of state laws covering the same subject. The federal interests in overseeing and enforcing the 340B Program could hardly be more dominant. Congress directed HHS to create an exclusive and comprehensive remedial scheme, which allows for federal enforcement as well as private ADR claims “to prevent overcharges and other violations of the discounted pricing requirements” and to govern disputes over 340B discount pricing. 42 U.S.C. §§ 256b(d)(1)(A), (d)(2)(A), (3); 42 C.F.R. §§ 10.3, 10.20. Just as private lawsuits by state actors seeking to apply state common law to enforce 340B requirements are “incompatible with the [340B] statutory regime,” so too is a state statute purporting to do the same thing. *Astra*, 563 U.S. at 113.

49. The state statute also is preempted by the federal 340B statute under conflict preemption principles. State laws are preempted under conflict principles where they stand as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. Conflict preemption is also found when a state law “interferes with the methods by which the federal statute was designed to” achieve those purposes and objectives. *International Paper Co. v. Ouellette*, 479 U.S. 481, 492, 494 (1987).

50. In particular, H.B. 1056 conflicts with federal law by purporting to unilaterally expand the universe of 340B-eligible sales well beyond those required by the statute itself. As the D.C. Circuit, the Third Circuit, the District Court for the District of Columbia, and the District Court for the District of Delaware recognized, the federal 340B statutory scheme does not require that a drug manufacturer honor unlimited contract pharmacy arrangements. *See Sanofi Aventis*, 58 F.4th at 703; *see also Novartis Pharms. Corp.*, 2021 WL 5161783, at *6. By Congressional design, whether to recognize covered entities' contract-pharmacy arrangements is purely a matter of manufacturer discretion. Yet H.B. 1056 purports to require manufacturers to make their 340B drugs available in connection with an unlimited number of contract pharmacy arrangements, in conflict with federal law as interpreted by multiple courts.

51. In addition, H.B. 1056 conflicts with the exclusive enforcement mechanism spelled out in the 340B statute. Congress made its intent plain: The federal 340B program must be enforced by a specialized federal administrative agency, and only that agency, through one of two centralized administrative processes: one driven by federal actors pursuing CMPs and other penalties, and the other driven by private claimants who file specified ADR claims before HRSA.

52. In *Astra USA*, county-operated 340B facilities filed a lawsuit against various drug manufacturers, alleging that they were charging prices in excess of those permitted under the manufacturers' PPAs. 563 U.S. 110. The plaintiffs' claims were styled as third-party beneficiary claims for breach of contract under state law. The Court rejected the plaintiffs' attempt to manufacture a state law right of action for violations of the 340B statute, noting: "Congress placed the Secretary (acting through her designate, HRSA) in control of § 340B's drug-price prescriptions. That control could not be maintained were potentially thousands of covered entities permitted to bring suits alleging errors in manufacturers' price calculations." *Id.* at 114.

53. As with the state common law remedy that the Supreme Court overturned in *Astra*, H.B. 1056 erects a substantial obstacle to that centralized federal process by creating a separate enforcement pathway for covered entities outside of the federal enforcement process. Maryland's law flouts the oversight scheme mandated by Congress and allows covered entities to bypass federal enforcement pathways. H.B. 1056 therefore is unenforceable under the Supremacy Clause. *See Gobeille v. Liberty Mut. Ins. Co.*, 577 U.S. 312, 326 (2016).

54. H.B. 1056 also is preempted by federal laws governing drug regulatory exclusivity periods and drug patent protection. With regard to regulatory exclusivity periods, Congress has spelled out a grand bargain: Manufacturers are driven to research, develop, and bring to market pharmaceutical products through a rigorous New Drug Application pathway, which requires manufacturers to submit clinical trials showing safety and efficacy. Brand name manufacturers do so on the promise that they will obtain a federally protected, exclusive right to sell their products for a specified period of time after approval, known as a "regulatory exclusivity period."

55. Congress directed the Food and Drug Administration (FDA) to recognize various periods of market exclusivity following approval of new drugs in order to reward manufacturers for innovation undertaken at considerable risk and expense. *See* 21 U.S.C. §§ 355(c)(3)(E)(ii), (j)(5)(F)(ii) (five years exclusivity for new chemical entities not previously approved by the FDA); *id.* § 355(c)(3)(E)(iii)-(iv), (j)(5)(F)(iii)-(iv) (three years exclusivity to reward additional clinical testing for new indications or to develop new dosages); *id.* § 355a (six months additional exclusivity for pediatric clinical testing); *id.* § 360cc (seven years exclusivity for "orphan drugs" used to treat rare diseases).

56. Once those exclusivity periods expire, generic manufacturers are permitted to utilize the drug development work done by innovator manufacturers in order to obtain streamlined

approval of generic products—without the need to show safety or efficacy through clinical trials. The public reaps the benefit of immediate access to a new product during the innovator manufacturer’s exclusivity period, and cheaper products once those periods expire.

57. A similar bargain underlies drug patent protection laws. Congress has plenary authority under the U.S. Constitution to establish and oversee the patent laws, which provide a system of incentives “[t]o promote the Progress of Science and useful Arts.” Art. I, § 8, cl. 8. In 1984, Congress enacted the “Hatch-Waxman” amendments to the FDCA, which among other things created a framework for patent litigation between brand manufacturers and generic manufacturers. Under the resulting framework, innovative manufacturers are “impelled to invest in creative effort” on the promise that they will obtain “a federally protected ‘exclusive right’” to sell their inventions for a limited period. *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1371–74 (Fed. Cir. 2007) (“*BIO*”). These patent exclusivity periods are distinctively federal and leave no room for state interference. “Where it is clear how the patent laws strike that balance in a particular circumstance, that is not a judgment the States may second-guess.” *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 152 (1989); *Southeastern Pennsylvania Transp. Auth. v. Gilead Scis., Inc.*, 102 F. Supp. 3d 688, 703 (E.D. Pa. 2015) (“Federal patent law contemplates the tradeoffs between exclusivity and access, and plaintiffs cannot use state law to adjust that balance by forcing Gilead to lower its prices or disgorge profits from the sale of its patented drugs.”).

58. State laws that cap or fix the prices at which patented drugs may be sold are preempted by federal patent law because they attempt to re-balance the carefully constructed federal statutory scheme that allocates rewards and incentives to innovator manufacturers. *See, e.g., Pharmaceutical Rsch. & Mfrs. of Am. v. District of Columbia*, 406 F. Supp. 2d 56, 60 (D.D.C.

2005), *aff'd sub nom. Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1371–74 (Fed. Cir. 2007).

59. In *BIO*, the Federal Circuit held that a D.C. law that capped the price of patented pharmaceutical products was preempted by the federal patent laws. *See Biotechnology Indus. Org.*, 496 F.3d 1362. “Inventors are impelled to invest in creative effort by the expectation that, through procurement of a patent, they will obtain a federally protected ‘exclusive right’ to exclude others from making, using, or selling embodiments of their invention.” *Id.* at 1372. The Court noted that the legislative history of the Hatch-Waxman Act supports this goal: “Patents are designed to promote innovation by providing the right to exclude others from making, using, or selling an invention. They enable innovators to obtain greater profits than could have been obtained if direct competition existed. These profits act as incentives for innovative activities.” *Id.* at 1373 (citing legislative history). The Court thus found that the “underlying determination about the proper balance between innovators’ profit and consumer access to medication, though, is exclusively one for Congress to make”—and a state may not “re-balance the statutory framework of rewards and incentives insofar as it relates to inventive new drugs.” *Id.* at 1374. “By penalizing high prices—and thus limiting the full exercise of the exclusionary power that derives from a patent—the District has chosen to re-balance the statutory framework of rewards and incentives insofar as it relates to inventive new drugs.” *Id.* The Court thus found the D.C. law preempted.

60. By requiring Novartis and other manufacturers of brand-name drugs to offer the 340B discount on sales made through contract pharmacy arrangements, even during the marketing exclusivity periods they are due under federal law, H.B. 1056 impermissibly diminishes the reward that federal law confers on manufacturers, which in turn redounds to the benefit of patients who gain access to Novartis’s life-saving and life-sustaining drug products.

VI. H.B. 1056 Violates the Dormant Commerce Clause.

61. H.B. 1056 also violates the dormant Commerce Clause. Under the Commerce Clause, Congress has the power to regulate commerce among the several states. U.S. Const. art. I, § 8, cl. 3. Although framed in terms of an affirmative grant to Congress, the Commerce Clause also limits “the power of the States to interfere with or impose burdens on interstate commerce.” *Arkansas Elec. Coop. Corp. v. Arkansas Pub. Serv. Comm’n*, 461 U.S. 375, 389 (1983) (citation omitted). This “dormant” component of the Commerce Clause means that offending state laws may not be enforced.

62. First, Maryland’s H.B. 1056 violates the dormant Commerce Clause because it imposes discriminatory extraterritorial burdens. The practical discriminatory effect of Maryland’s law provisions is to directly regulate out-of-state transactions between manufacturers like Novartis and its distributing partners and national-chain pharmacies.

63. Drug distribution is by its very nature an interstate phenomenon. H.B. 1056 prohibits *manufacturers* from refusing to provide the 340B discount in connection with transactions involving contract pharmacies. But manufacturers give the 340B discount to wholesalers in a financial transaction that typically takes place between two out-of-state entities.

64. In *Association for Accessible Medicines v. Frosh*, 887 F.3d 664, 674 (4th Cir. 2018), the Fourth Circuit held that a Maryland law prohibiting a manufacturer or wholesaler from engaging in “price gouging” in the sale of prescription drugs violated the dormant Commerce Clause. The Court noted that manufacturers and wholesalers were largely located out of state, and that, by focusing on manufacturers and wholesalers, the law targeted up-stream transactions occurring out of State. *Id.* at 672 (noting that “the Act is effectively a price control statute that

instructs manufacturers and wholesale distributors as to the prices they are permitted to charge in transactions that do not take place in Maryland.”).

65. Similarly, in *Pharmaceutical Research & Mfrs. of Am. v. District of Columbia*, 406 F. Supp. 2d 56, 70 (D.D.C. 2005) (“*PhRMA*”)—the district court decision that led to the *BIO* Federal Circuit decision described above—the District Court for the District of Columbia invalidated a state drug pricing law on dormant Commerce Clause grounds. The law prohibited manufacturers from a selling drug that “results in the prescription drug being sold in the District for an excessive price.” *Id.* at 68. The district court noted that “Plaintiffs’ members manufacture patented prescription drugs wholly outside the District of Columbia and are neither headquartered in the District, nor operate warehouses in the District. Thus, in practice, plaintiffs’ members sell ‘the overwhelming bulk’ of their patented prescription drugs in out-of-state transactions to wholesalers or large retail chains that maintain their own warehousing and retail distribution system.” *Id.* The court therefore found that a state drug pricing law “effect[ed] an impermissible extraterritorial reach” and violated the dormant Commerce Clause. *Id.* at 70.

66. Like the manufacturers in *Frosh* and *PhRMA*, Novartis is not located in Maryland. Novartis typically sells its products to national wholesalers and distributors located around the country. In turn, the wholesalers sell the products to national-chain pharmacies—whose headquarters are also typically located outside the state. Novartis’s products are eventually sold by contract pharmacies to patients located in Maryland. The 340B discount travels back through the chain in the opposite direction: Covered entities file a chargeback with wholesalers. Wholesalers then separately file a chargeback with manufacturers.

67. While Novartis’s products are eventually sold by contract pharmacies to patients in Maryland, H.B. 1056 targets not *that* transaction but instead the sale from manufacturers to

wholesalers. In other words, the conduct that Maryland’s law “targets is the upstream pricing and sale of prescription drugs”—which “effectively seeks to compel manufacturers to act in accordance with” H.B. 1056 outside of the state. *Association for Accessible Medicines v. Frosh*, 887 F.3d 664, 671–672 (4th Cir. 2018).

68. H.B. 1056 also is discriminatory. The Supreme Court has recently held that at the “very core” of the dormant Commerce Clause is a simple “antidiscrimination principle”: No matter how earnestly a state wishes to enact “regulatory measures designed to benefit in-state economic interests,” its legislation cannot advance the sort of “economic protectionism” that privileges its homegrown commercial interests. *National Pork Producers Council v. Ross*, 598 U.S. 356, 377 (2023). A law that discriminates against interstate commerce is per se invalid unless the state has no other means to advance a legitimate local purpose. A state statute may discriminate against interstate commerce on its face, in its practical effect, or in its purpose.

69. H.B. 1056 has both a discriminatory intent and effect: The goal is to protect in-state industries (hospitals and pharmacies) by forcing out-of-state manufacturers to give them a steep discount. That privileges in-state pharmacies while significantly burdening out-of-state manufacturers like Novartis.

70. Because Maryland’s law advantages in-state interests by making it unlawful for out-of-state firms to refuse extending through Maryland pharmacies a below-market bargain—or to refuse to bargain at all—it violates the dormant Commerce Clause. *Pork Producers*, 598 U.S. at 370.

71. This economic protectionism is especially profitable for the entities that reap its benefits, with “the average profit margin of these” in-state contract “pharmacies on commonly dispensed 340B drugs” reaching “an astounding 72%, compared to 22% for non-340B drugs.”

Peter J. Pitts & Robert Popovian, *340B and the Warped Rhetoric of Healthcare Compassion*, available at <https://www.fdli.org/2022/09/340b-and-the-warped-rhetoric-of-healthcare-compassion/>.

72. Maryland has no valid justification for discriminating against out-of-state manufacturers. Forcing Novartis to deliver its 340B-discounted drugs to contract pharmacies at discounted prices to which they are not entitled under the 340B statute advances the economic interests of private pharmacies, with no benefit to patients or the public. Even if it did, there are other means for advancing its purported purpose that do not involve discrimination. A state may, for example, give grants directly to hospitals and pharmacies it wishes to assist.

73. H.B. 1056 also falters under the balancing test the Supreme Court announced in *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970). See *Truesdell v. Friedlander*, 80 F.4th 762, 768 (6th Cir. 2023) (explaining post-*Pork Producers* that, even if a law does not discriminate, a court must ask “whether it nevertheless inflicts a ‘substantial harm’ on interstate commerce” under *Pike*); *Restaurant L. Ctr. v. City of New York*, 90 F.4th 101, 118 (2d Cir. 2024) (same). The burdens the law imposes on interstate commerce are clearly excessive in relation to its putative local benefits. Maryland’s law uniquely tilts the bargaining power in favor of in-state pharmacies and covered entities at the expense of out-of-state drug manufacturers. Those burdens will only compound as more states follow suit. A race to the bottom is taking shape already: Arkansas, Louisiana, West Virginia, Mississippi, Kansas, and Minnesota have recently adopted comparable statutes. Ark. Code Ann. § 23-92-601 *et seq.*; La. Rev. Stat. §§ 40:2881–2886.³

74. Equally problematic, manufacturers now must contend with a patchwork of state laws with different terms and different requirements, each purporting to regulate transactions that

³ Several legal challenges have been filed relating to these other laws.

are primarily nationwide in nature. Some states apply the 340B discount to transactions involving pharmacies located in the state; others apply the discount to pharmacies located outside of the state but licensed in state. Some states have exceptions for drugs required to be distributed through specialty pharmacies due to REMS; others do not. The penalties and remedies available for violation vary from state to state.

75. Drug manufacturers typically enter into nationwide contracts with wholesalers and distributors, which in turn typically enter into contracts with national pharmacy chains. It is virtually impossible for manufacturers and wholesalers to map multiple overlapping and inconsistent state laws onto those nationwide contracts without creating conflicts and forcing violations of competing state laws. *See Healy v. Beer Inst., Inc.*, 491 U.S. 324, 336 (1989) (“[T]he practical effect of the statute must be evaluated” by considering “how the challenged statute may interact with the legitimate regulatory regimes of other States and what effect would arise if not one, but many or every, State adopted similar legislation.”).

76. As more states enact their own variations on H.B. 1056, the burden on interstate commerce will snowball. Novartis will be forced to prepare and monitor different contract pharmacy policies in every state, a result that is equal parts unsustainable and unlawful, because it elevates state-specific interests in precisely the way the dormant Commerce Clause prohibits. *See Pork Producers*, 598 U.S. at 377 (“[T]he *Pike* line serves as an important reminder that a law’s practical effects may also disclose the presence of a discriminatory purpose.”); *see, e.g., Frosh*, 887 F.3d at 670 (finding a state statute violated the dormant Commerce Clause, in part, where the statute, “if similarly enacted by other states, would impose a significant burden on interstate commerce involving prescription drugs”).

VII. H.B. 1056 Will Cause Concrete and Imminent Harm to Novartis.

77. Novartis will be irreparably harmed unless this Court enjoins Defendants from enforcing H.B. 1056.

78. If H.B. 1056 is not enjoined, Novartis will be exposed to unlawful state-law obligations and will risk violating Maryland law by continuing with a policy that fully complies with federal law (as determined by multiple federal courts). A regulated entity may be irreparably injured in the face of the threatened enforcement of a preempted law. *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 381 (1992).

79. Failure to comply with the state law will also subject Novartis to state administrative enforcement proceedings that are themselves unlawful, for the reasons stated above. That too creates irreparable harm.

80. Maryland's law deprives Novartis of its rights under the carefully, federally defined terms of the 340B program and under federal drug laws. H.B. 1056 threatens to impose significant penalties upon Novartis if it does not capitulate to Maryland's attempt to circumvent the terms of that federal program. The deprivation of constitutional rights constitutes irreparable injury for purposes of a preliminary injunction.

81. Novartis has no readily apparent way to recover monetary relief for the wrongfully issued 340B-discounts. HRSA's position is that a manufacturer may only seek recovery through the federal ADR process only on claims relating to duplicate discounts and drug diversion. 42 U.S.C. § 256b(d)(3)(A). The ADR process thus provides no path for Novartis to challenge a state impermissibly allowing a contract pharmacy to receive its drugs at 340B-discounted prices. With no available remedy at law, Novartis will suffer irreparable absent prospective injunctive relief.

82. Granting injunctive relief here would not harm Defendants, as it is well-established that states maintain no interest in enforcing a statute that violates federal law. Injunctive relief also would serve the public interest. The public has a substantial interest in seeing that federal law is enforced and not countenancing state efforts to reset the metes and bounds of participation in federal healthcare programs.

CLAIMS FOR RELIEF

COUNT I

(Declaratory/Injunctive Relief— Preemption Under the Supremacy Clause, U.S. Const. art. VI, cl. 2)

83. Novartis realleges, reasserts, and incorporates by reference herein each of the foregoing allegations as though set forth fully herein.

84. The Supremacy Clause of the U.S. Constitution provides that Federal law is “the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.” U.S. Const. art. VI, cl. 2.

85. H.B. 1056 is preempted by the federal 340B statute and by federal drug laws.

86. As a matter of field preemption, H.B. 1056 is preempted because it attempts to regulate in a field that Congress has fully occupied.

87. H.B. 1056 also is preempted because it imposes a substantial obstacle to the achievement of federal purposes and objectives under the 340B statute.

88. And by purporting to reduce the value of the exclusivity periods and patent terms that the FDCA and federal patent laws guarantee to qualifying drug manufacturers, H.B. 1056 is preempted under conflict preemption principles because it interferes with the careful balance of rewards and incentives that Congress crafted—a framework in which States simply play no role.

COUNT II
(Declaratory/Injunctive Relief—
Dormant Commerce Clause, U.S. Const. art. I, § 8, cl. 3)

89. Novartis realleges, reasserts, and incorporates by reference herein each of the foregoing allegations as though set forth fully herein.

90. Under the Commerce Clause, Congress has the power to regulate commerce among the several states. U.S. Const. I, § 8, cl. 3. The “dormant” component of the Commerce Clause limits the power of the States to interfere with or impose burdens on interstate commerce.

91. H.B. 1056 regulates wholly outside of the state by regulating transactions between manufacturers like Novartis and its out-of-state wholesalers.

92. H.B. 1056 is also discriminatory. No state can advance economic protectionism to benefit its homegrown commercial interests while burdening out-of-state competitors. Thus, a law that discriminates against interstate commerce is per se invalid unless the state has no other means to advance a legitimate local purpose.

93. H.B. 1056 is discriminatory on several fronts. It privileges in-state pharmacies while significantly burdening out-of-state manufacturers like Novartis.

94. H.B. 1056 has no legitimate local purpose for discriminating against out-of-state manufacturers like Novartis. But even if Maryland could offer a legitimate purpose, there are many other means for advancing its purpose that do not involve discrimination.

95. H.B. 1056 also falters under the balancing test the Supreme Court announced in *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970). The burdens Maryland’s law imposes on interstate commerce are clearly excessive in relation to its putative local benefits. Maryland’s law uniquely tilts the bargaining power in favor of in-state pharmacies at the expense of out-of-state drug manufacturers like Novartis. Those burdens will only compound as more states follow suit.

96. H.B. 1056 therefore is unconstitutional under the dormant Commerce Clause.

PRAYER FOR RELIEF

For the foregoing reasons, Novartis prays for the following relief:

A. A declaration pursuant to 28 U.S.C. § 2201 that H.B. 1056 is preempted by federal law and is thus null, void, and unenforceable;

B. A declaration pursuant to 28 U.S.C. § 2201 that H.B. 1056 violates the Commerce Clause and is unconstitutional as applied to Novartis;

C. Temporary, preliminary, and permanent injunctive relief vacating H.B. 1056 and enjoining Defendants from implementing and/or enforcing H.B. 1056 against Novartis or any of its affiliates, officers, agents, representatives, or contractors;

D. Temporary, preliminary, and permanent injunctive relief enjoining Defendants from seeking civil or criminal penalties, equitable relief, or any other remedy based on an alleged violation under H.B. 1056 by Novartis or any of its affiliates, officers, agents, representatives, or contractors;

E. An order awarding Novartis attorneys' fees, costs, and expenses, as appropriate; and

F. Such other and further relief as the Court deems just and proper.

Respectfully submitted,

/s/ Susan M. Cook

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**Pro Hac Vice Motion Forthcoming*

***Application for Admission Forthcoming*


Dated: May 29, 2024

Attorneys for Novartis Pharmaceuticals Corporation

VERIFICATION

I, the undersigned, having read the allegations of the foregoing Verified Complaint, hereby declare under penalty of perjury and pursuant to 28 U.S.C. § 1746 that the factual allegations asserted in the Verified Complaint are true and correct.

Executed this 29th day of May, 2024.


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